

2018 Current Fiscal Year Report: Tick-Borne Disease Working Group

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1. Department or Agency

Department of Health and Human Services

2. Fiscal Year

2018

3. Committee or Subcommittee

Tick-Borne Disease Working Group

3b. GSA Committee No.

2619

4. Is this New During Fiscal Year?

No

5. Current Charter

08/10/2017

6. Expected Renewal Date

08/10/2019

7. Expected Term Date

12/13/2022

8a. Was Terminated During Fiscal Year?

No

8b. Specific Termination Authority

Section 2062 of the 21st Century Cures Act

8c. Actual Term Date

9. Agency Recommendation for Next Fiscal Year

Continue

10a. Legislation Req to Terminate?

No

10b. Legislation Pending?

Not Applicable

11. Establishment Authority Statutory (Congress Created)

12. Specific Establishment Authority

Section 2062 of the 21st Century Cures Act

13. Effective Date

12/13/2016

14. Committee Type

Continuing

14c. Presidential?

No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports

No Reports for this Fiscal Year

17a. Open 7 Meetings and Dates 17b. Closed 0 17c. Partially Closed 0 Other Activities 0 17d. Total 7

Purpose	Start	End
At the inaugural meeting of the Tick-Borne Disease Working Group, the members focused on plans to submit a report to the HHS Secretary and Congress that will address a number of issues related to tick-borne diseases. Planning also included developing plans to solicit stakeholder input and establish subcommittees.	12/11/2017	12/11/2017
The purpose of this meeting was to: receive key stakeholder perspectives from health care professionals, public health officials, and public comments; discuss the roles and responsibilities of the Working Group; review the charter; determine Working Group values, vision, and mission statement; and review the work plan including timeline and subcommittee creation.	12/12/2017	12/12/2017
To discuss the timeline for the Working Group's report to Congress and HHS Secretary; vote on the mission, vision and value of the Working Group; review roles and tasks of subcommittees and subcommittee members; and have subcommittee breakout sessions and report back.	02/12/2018	02/12/2018
The primary purpose of this meeting was to receive reports from the Working Group subcommittees and begin to prioritize issues from these reports for inclusion in the 2018 Report to Congress.	05/10/2018	05/10/2018
During this meeting, the Working Group discussed the information provided during the previous meeting, as well as paths forward. This included gathering areas of agreement and controversy, and breaking down each subcommittees report to determine inclusion into the report to Congress.	05/15/2018	05/16/2018

The Working Group used this meeting to review all drafts chapters in the 2018 report, which included conversation regarding the use of inventories and infographics, as well as all technical issues being faced.

06/21/2018 - 06/21/2018

The Working Group reviewed and voted on each chapter of the 2018 Report to Congress.

07/24/2018 - 07/24/2018

Number of Committee Meetings Listed: 7

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	\$0.00	\$0.00
18a(2). Personnel Pmts to Federal Members	\$0.00	\$0.00
18a(3). Personnel Pmts to Federal Staff	\$250,560.00	\$260,580.00
18a(4). Personnel Pmts to Non-Member Consultants	\$0.00	\$0.00
18b(1). Travel and Per Diem to Non-Federal Members	\$14,000.00	\$7,280.00
18b(2). Travel and Per Diem to Federal Members	\$0.00	\$0.00
18b(3). Travel and Per Diem to Federal Staff	\$0.00	\$0.00
18b(4). Travel and Per Diem to Non-member Consultants	\$0.00	\$0.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	\$400,000.00	\$416,000.00
18d. Total	\$664,560.00	\$683,860.00
19. Federal Staff Support Years (FTE)	2.00	2.00

20a. How does the Committee accomplish its purpose?

The 21st Century Cures Act (Public Law 114-255) was enacted to advance the research and development of new therapies and diagnostics and make substantial federal investments in a wide range of health priorities. The Department of Health and Human Services has responsibility for ensuring the conduct of and support for epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases. Under Section 2062 of the 21st Century Cures Act, the Secretary of Health and Human Services is mandated to establish the Tick-Borne Disease Working Group. The Working Group assists HHS in its effort to properly address this important public health concern. The Working Group will provide expertise and review all activities being undertaken by HHS that pertain to tick-borne diseases. It is stipulated in the authorizing legislation and the committee charter that the Working Group will develop or update a summary of ongoing activities, including research, related to tick-borne diseases that are being undertaken by HHS and other federal agencies and offices; make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and solicit input from States, localities, and non-government entities. Two years after enactment of P.L. 114-255, the Working Group is required to submit a report that contains its findings and recommendations to the Secretary and the appropriate Congressional committees.

20b. How does the Committee balance its membership?

The Working Group is authorized to have 14 members. The membership will represent a diversity of scientific disciplines and views from the appropriate federal agencies and

non-federal entities. The composition of the Working Group consists of seven federal members and seven non-federal public members. Individuals who are selected to serve as non-federal public members may represent the following categories: physicians and other health care providers with experience in diagnosing and treating tick-borne diseases; scientists or researchers with expertise; patients and their family members; and members of nonprofit organizations that advocate for patients with respect to tick-borne diseases. The federal member category will consist of one or more representatives from the following HHS organizational components: Office of the Assistant Secretary for Health, Centers for Disease Prevention and Control, Food and Drug Administration, and the National Institutes of Health. Invitations of membership may be extended to other agencies and offices of the Department of Health and Human Services and other individuals as determined by the Secretary to be appropriate and beneficial to the functioning of the Working Group. The Secretary identified that the additional federal members will be from the Centers of Medicare and Medicaid Services, White House, Office of Management and Budget, and the Department of Defense.

20c. How frequent and relevant are the Committee Meetings?

It is stipulated in the charter that the Working Group will meet not less than two times a year. The Working Group will discuss topics and issues that are pertinent to its mission during these meetings. The Working Group's deliberations during the meetings will be critical for developing the annual report that must be submitted to the Secretary and the designated Congressional committees to comply with the authorizing statute.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The Tick-Borne Disease Working Group is a non-discretionary federal advisory committee. Establishment of the Working Group was statutorily mandated by Congress. The mandate to establish the Working Group can be found in the 21st Century Cures Act (Public Law 114-255) under Section 2062. This legislation was enacted to advance the research and development of new therapies and diagnostics and make substantial federal investments in a wide range of health priorities. The statute stipulates that the Working Group is to be comprised of representatives of appropriate federal agencies and non-federal entities to help ensure that there is a diversity of scientific disciplines and views to provide input on the efforts being undertaken by HHS to properly address the issues and concerns regarding the conduct and support research on vector-borne diseases, including tick-borne diseases. The diversity of the membership helps to ensure interagency coordination and minimize overlap, and to examine research priorities.

20e. Why is it necessary to close and/or partially closed committee meetings?

All meetings of the Working Group will be open to the public unless it is determined that the topics to be discussed are confidential and sensitive in nature.

21. Remarks

The Working Group convened for its first meeting on December 11, 2017, and has had six subsequent meetings. Two years after enactment of P.L. 114-255, the Working Group is required to submit a report that contains its findings and recommendations to the Secretary and the appropriate Congressional committees. This report is expected to be delivered to Congress in November 2018. In the meetings section of this report, two different meetings were held on consecutive days (12/11/17 and 12/12/17) and advertised in the Federal Register as such.

Designated Federal Officer

James J Berger Senior Advisor for Blood and Tissue Policy, Office of HIV/AIDS and Infectious Disease Policy

Committee Members	Start	End	Occupation	Member Designation
Adams, Wendy	12/11/2017	03/10/2019	Research Grant Advisor	Special Government Employee (SGE) Member
Aucott, John	12/11/2017	03/10/2019	Director John Hopkins Lyme Disease Clinical Research Center	Special Government Employee (SGE) Member
Beard, Ben	12/11/2017	12/13/2022	CDC	Regular Government Employee (RGE) Member
Cooper, Scott	12/11/2017	12/13/2022	CMS	Regular Government Employee (RGE) Member
Dixon, Dennis	12/11/2017	12/13/2022	NIH	Regular Government Employee (RGE) Member
Honey, Kristen	12/11/2017	12/13/2022	OMB	Regular Government Employee (RGE) Member
Horowitz, Richard	12/11/2017	03/10/2019	Physician	Special Government Employee (SGE) Member
Jones, Estella	12/11/2017	12/13/2022	FDA	Regular Government Employee (RGE) Member
Nigrovic, Lise	12/11/2017	03/10/2019	Physician	Special Government Employee (SGE) Member
Richards, Allen	12/11/2017	12/13/2022	Senior Scientist and Research Coordinator	Regular Government Employee (RGE) Member
Sabatino, Robert	05/02/2018	08/09/2019	Founder, Lyme Society Inc	Special Government Employee (SGE) Member
Singh, Vanila	12/11/2017	12/13/2022	Chief Medical Officer	Regular Government Employee (RGE) Member
Smith, Patricia	12/11/2017	03/10/2019	President Lyme Disease Association	Special Government Employee (SGE) Member
Smith, Robert	01/26/2018	04/25/2019	Physician	Special Government Employee (SGE) Member
Vanderhoof-Forschner, Karen	12/11/2017	03/06/2018	JD	Special Government Employee (SGE) Member

Number of Committee Members Listed: 15

Narrative Description

The 21st Century Cures Act (Public Law 114-255) was enacted to advance the research and development of new therapies and diagnostics and make substantial federal investments in a wide range of health priorities. The Department of Health and Human Services has responsibility for ensuring the conduct of and support for epidemiological, basic, translational, and clinical research related to vector-borne diseases, including tick-borne diseases. Under Section 2062 of the 21st Century Cures Act, the Secretary of Health and Human Services is mandated to establish the Tick-Borne Disease Working Group. The Working Group will assist HHS in its effort to properly address this important public health concern. The Working Group will provide expertise and review all activities being undertaken by HHS that pertain to tick-borne diseases. It is stipulated in the authorizing legislation and the committee charter that the Working Group will develop or update a summary of ongoing activities, including research, related to tick-borne diseases that are being undertaken by HHS and other federal agencies and offices; make recommendations to the Secretary regarding any appropriate changes or improvements to such activities and research; and solicit input from States, localities, and non-government entities. Two years after enactment of P.L. 114-255, the Working Group is required to submit a report that contains its findings and recommendations to the Secretary and the appropriate Congressional committees.

What are the most significant program outcomes associated with this committee?

Checked if Applies

Improvements to health or safety	<input checked="" type="checkbox"/>
Trust in government	<input checked="" type="checkbox"/>
Major policy changes	<input checked="" type="checkbox"/>
Advance in scientific research	<input checked="" type="checkbox"/>
Effective grant making	<input type="checkbox"/>
Improved service delivery	<input checked="" type="checkbox"/>
Increased customer satisfaction	<input checked="" type="checkbox"/>
Implementation of laws or regulatory requirements	<input type="checkbox"/>
Other	<input type="checkbox"/>

Outcome Comments

What are the cost savings associated with this committee?

Checked if Applies

None	<input type="checkbox"/>
Unable to Determine	<input checked="" type="checkbox"/>

Under \$100,000	<input type="checkbox"/>
\$100,000 - \$500,000	<input type="checkbox"/>
\$500,001 - \$1,000,000	<input type="checkbox"/>
\$1,000,001 - \$5,000,000	<input type="checkbox"/>
\$5,000,001 - \$10,000,000	<input type="checkbox"/>
Over \$10,000,000	<input type="checkbox"/>
Cost Savings Other	<input type="checkbox"/>

Cost Savings Comments

Cost savings dependent on action taken on recommendations

What is the approximate Number of recommendations produced by this committee for the life of the committee?

28

Number of Recommendations Comments

28 recommendations will be published in the 2018 Report to Congress.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

0%

% of Recommendations Fully Implemented Comments

The 2018 report has not yet been sent to Congress.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

0%

% of Recommendations Partially Implemented Comments

The 2018 report has not yet been sent to Congress.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☐ No ☒ Not Applicable ☐

Agency Feedback Comments

The 2018 report has not yet been sent to agency for review.

What other actions has the agency taken as a result of the committee's advice or recommendation?

Checked if Applies

- | | |
|-----------------------------------|--------------------------|
| Reorganized Priorities | <input type="checkbox"/> |
| Reallocated resources | <input type="checkbox"/> |
| Issued new regulation | <input type="checkbox"/> |
| Proposed legislation | <input type="checkbox"/> |
| Approved grants or other payments | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Action Comments

Not applicable

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

Not Applicable

How is access provided to the information for the Committee's documentation?

Checked if Applies

- | | |
|---------------------------|-------------------------------------|
| Contact DFO | <input checked="" type="checkbox"/> |
| Online Agency Web Site | <input type="checkbox"/> |
| Online Committee Web Site | <input checked="" type="checkbox"/> |
| Online GSA FACA Web Site | <input checked="" type="checkbox"/> |
| Publications | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Access Comments

N/A